

2018 Current Fiscal Year Report: Cardiovascular and Renal Drugs Advisory Committee

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1. Department or Agency		2. Fiscal Year	
Department of Health and Human Services		2018	
3. Committee or Subcommittee		3b. GSA Committee No.	
Cardiovascular and Renal Drugs Advisory Committee		817	
4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	08/27/2018	08/27/2020	
8a. Was Terminated During Fiscal Year?	8b. Specific Termination Authority	8c. Actual Term Date	
No			
9. Agency Recommendation for Next Fiscal Year	10a. Legislation Req to Terminate?	10b. Legislation Pending?	
Continue	Not Applicable	Not Applicable	
11. Establishment Authority Authorized by Law			
12. Specific Establishment Authority	13. Effective Date	14. Committee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No
15. Description of Committee Scientific Technical Program Advisory Board			
16a. Total Number of Reports	No Reports for this Fiscal Year		
17a. Open Meetings and Dates	17b. Closed Meetings and Dates	17c. Partially Closed Meetings and Dates	17d. Total Meetings and Dates
No Meetings			

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$0.00	\$6,562.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$144,547.00	\$142,281.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$5,468.00
18b(1). Travel and Per Diem to Non-Federal Members	\$0.00	\$0.00
18b(2). Travel and Per Diem to Federal Members	\$0.00	\$0.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$0.00	\$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	\$36,137.00	\$35,570.00
18d. Total	\$180,684.00	\$189,881.00

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

The committee is balanced with respect to various aspects of cardiology. Committee members have expertise in cardiology, hypertension, arrhythmia, angina, congestive heart failure, diuresis, and biostatistics. In addition the committee has one consumer member and may include one non-voting member representing Industry.

20c. How frequent and relevant are the Committee Meetings?

The committee did not meet during FY-18. It is expected that the committee will meet one time during FY-19.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the committee are drawn from academia, research and/or clinical practice. Their advice and input lends credibility to FDA regulatory decisions. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientist on a full-time basis at a maximum rate of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?

The committee held no closed meetings during FY-18.

21. Remarks

Although this committee did not meet in FY 2018, considerable time was devoted to reappointing current members, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was spent in the routine care and maintenance of the committee: the development of a financial report for this website; updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members and providing ethics training. Since the Committee did not meet, no reporting was required.

Designated Federal Officer

Jennifer A Shepherd Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Alexander, John	07/01/2016	06/30/2020	Professor of Medicine Department of Medicine, Division of Cardiology Duke University School of Medicine	Special Government Employee (SGE) Member
Arkus, Bonnie	02/05/2015	06/30/2018	CONSUMER REPRESENTATIVE; President, Women's Heart Foundation	Special Government Employee (SGE) Member
Chacko, Matthews	09/14/2015	06/30/2019	Assistant Professor of Medicine, Division of Cardiology, Johns Hopkins University and Hospital	Special Government Employee (SGE) Member
Davis, Barry	02/05/2015	06/30/2019	Professor of Biostatistics; Director, Coordinating Center for Clinical Trials; University of Texas School of Public Health	Special Government Employee (SGE) Member
Gibson, Charles	08/24/2017	06/30/2021	Professor of Medicine, Harvard Medical School	Special Government Employee (SGE) Member
Harrington, Robert	04/18/2016	06/30/2018	Professor and Chairman, Stanford University School of Medicine	Special Government Employee (SGE) Member
Lewis, Julia	08/24/2017	06/30/2021	Professor of Medicine, Vanderbilt University School of Medicine	Special Government Employee (SGE) Member
Mandrola, John.	11/14/2017	06/30/2020	Electrophysiologist, Baptist Medical Associates	Special Government Employee (SGE) Member
Nachman, Patrick	04/18/2016	06/30/2019	Professor of Medicine, University of North Carolina at Chapel Hill	Special Government Employee (SGE) Member
Packer, Milton	07/01/2016	06/30/2020	Distinguished Scholar in Cardiovascular Medicine Baylor Heart and Vascular Institute Baylor University Medical Center	Special Government Employee (SGE) Member
Ridker, Paul	11/14/2017	06/30/2021	Eugene Braunwald Professor of Medicine, Harvard Medical School	Special Government Employee (SGE) Member
Wasserman, Scott	02/29/2016	10/31/2019	Vice President, Global Development; Cardiovascular and Metabolic Therapeutic Area Head and Head of Development Design Center	Representative Member

Number of Committee Members Listed: 12

Narrative Description

FDA's strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Cardiovascular and Renal Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of marketed and investigational

human drug products for use in the treatment of cardiovascular and renal diseases and making appropriate recommendations to the Commissioner of the Food and Drug Administration. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

Checked if Applies

Improvements to health or safety	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input checked="" type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input type="checkbox"/>
Increased customer satisfaction	<input checked="" type="checkbox"/>
Implementation of laws or regulatory requirements	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

Outcome Comments

N/A

What are the cost savings associated with this committee?

Checked if Applies

None	<input type="checkbox"/>
Unable to Determine	<input checked="" type="checkbox"/>
Under \$100,000	<input type="checkbox"/>
\$100,000 - \$500,000	<input type="checkbox"/>
\$500,001 - \$1,000,000	<input type="checkbox"/>
\$1,000,001 - \$5,000,000	<input type="checkbox"/>
\$5,000,001 - \$10,000,000	<input type="checkbox"/>
Over \$10,000,000	<input type="checkbox"/>
Cost Savings Other	<input type="checkbox"/>

Cost Savings Comments

The utilization of the Cardiovascular and Renal Drugs Advisory Committee enables the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is

difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

53

Number of Recommendations Comments

The committee has made 53 recommendations from FY-03 through FY-18.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

79%

% of Recommendations Fully Implemented Comments

The function of the advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

9%

% of Recommendations Partially Implemented Comments

The function of the advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☒ No ☐ Not Applicable ☐

Agency Feedback Comments

It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

Reorganized Priorities	<input checked="" type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input checked="" type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Action Comments

FDA approves or chooses not to approve an investigational new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

Checked if Applies

Contact DFO	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>
Online Committee Web Site	<input checked="" type="checkbox"/>
Online GSA FACA Web Site	<input checked="" type="checkbox"/>
Publications	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

Access Comments

N/A